JAN - 4 2007

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:

Company Name : GEMORE TECHNOLOGY CO., LTD.
Contact person: Boden S.P. Lai
Address : 11FL., NO. 29-5, Sec. 2, Chung Cheng E. RD., Tan Shui, Taipei Hsien, Taiwan
TEL No. : 886-2-8809-1799
Fax No. : 886-2-8809-1781
E-mail address : gemore@anet.net.tw
Date of Summary Preparation: August 30, 2006.

2. Device Identification:

Classification Name: Neurostimulation Electrodes

Trade/Proprietary Name: Gemore Reuseable Self Adhesive Electrode / Wire series, Snap series and Double side series

Predicate devices: K052875 (Summit Manufacturing L.L.C)
K050788 (EVERLIFE Medical Instrument Co., Ltd.)

3. Device Description

Gemore Reuseable Self Adhesive Electrode / Wire series, Snap series and Double side series are non-sterile, disposable laminated, flexible structures composed of materials commonly used in this application:

First Layer – White spun laced nonwoven tape or White 1/32" thick Polyethylene foam or a polypropylenc substrate, coated with biocompatible adhesive.
Second Layer – Conductive plastic film.
Third Layer – Biocompatible conductive hydrogel coupling media

The electrodes are designed for single-patient/multiple application use. Because of the adhesive nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin. The electrode has one type of connection point that can be used to connect the stimulation device to the electrodes. This connection point is compatible with all standard, marketed Neurostimulation devices.

For the electrical connection, Gemore provides three different types:
Snap Series – Snap connection – 1.65" standard size of mail. Snap is provided to connect to the wire female snap.
Wire Series – Lead wire assembly – 4.5" ~ 6" wire with .080 in. diameter female socket connected to one side of the wire.
Double side series – adhesive gel was also provided at the reverse side of skin contact. With this adhesive side, the electrode can be mounted on the electricity conductive surface of device without additional lead wire or snap.

4. Predicate Technological Characteristics Comparison:

Gemore Reuseable Self Adhesive Electrode / Wire series, Snap series and Double side series are technologically equivalent to the predicate devices. They are physically and technically similar to the those currently being marketed for "Neurostimulation" i.e., TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Since currently the abovementioned devices are capable of being sold as both prescription and OTC medical device, we claimed that our electrodes are to be sold at both prescription and OTC application so as to fit that marketing requirement.

5. Safety and Effectiveness:

Gemore Reuseable Self Adhesive Electrode / Wire series, Snap series and Double side series are as safe and effective as the K052875 (Summit Manufacturing L.L.C) and K050788 (EVERLIFE Medical Instrument Co., Ltd.) which were previously found to be substantially equivalent via 510(k) Premarket Notifications.

The first safety issue considered was whether the gel, which is used to adhere the electrode to the skin and which is the only portion of the electrode to maintain skin contact, would cause any skin irritation. The Everlife series gel (K050788) or the Amgel 700 Series gels (file number K983741), which may be used in the skin contact part for this family of electrodes, All of them have passed the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact.

For the electricity performance, we have conducted and completed the electrical safety testing according to the chosen performance standard, ANSI/AAMI EC12. The testing report was included in this submission.

Based on the aforementioned information. Gemore considers its Reusable Self Adhesive electrodes to be as safe and effective as the predicate devices as well as multiple other TENS/NMES electrodes currently being marketed including those manufactured by: K052875 (Summit Manufacturing L.L.C) and K050788 (EVERLIFE Medical Instrument Co., Ltd.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gemore Technology Co., Ltd.
% Boden S. P. Lai
General Manager
11FL., NO. 29-5, Sec. 2,
Chung Cheng E. Rd.
Tan Shui, Taipei Hsien, Taiwan

JAN 04 2007

Re: K062675
Trade/Device Name: Gemore Reuseable Self Adhesive Electrode/Wire series, Snap series, and Double side series
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: November 24, 2006
Received: November 28, 2006

Dear Boden S.P. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K062675

Device Name: Gemore Reuseable Self Adhesive Electrode / Wire series, Snap series, and Double side series

Indications For Use:

The Gemore Reuseable Self Adhesive Electrode / Wire series, Snap series, and Double side series are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Gemore Reuseable Self Adhesive Electrode / Wire series, snap series, and double side series are designed and intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Prescription Use √ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062675